



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1992]

### **Prospective Grant of an Exclusive Patent License: Field-Deployable Mass Spectrometer Diagnostic for SARS, SARS-CoV-2 and Other Viruses, Bacteria and Bacterial Serovar, and Drug Impurities**

**AGENCY:** Food and Drug Administration

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the invention embodied in the U.S. Patent listed in the Supplementary Information section of this notice to Advion, Inc. located in Ithaca, New York.

**DATES:** Only written comments and/or applications for a license which are received by the Food and Drug Administration's Technology Transfer Program on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered.

**ADDRESSES:** Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Ken Millburne, Food and Drug Administration Technology Transfer Program, Bldg. 1, Rm. 4213, Silver Spring, MD 20993, 240-478-1662; email: [Kenneth.millburne@fda.hhs.gov](mailto:Kenneth.millburne@fda.hhs.gov).

### **SUPPLEMENTARY INFORMATION:**

#### Intellectual Property

FDA Reference No.: E-2011-021: "Direct Impact Ionization (DII) Mass Spectrometry."

- I. U.S. Non-Provisional Application 13/271,182, filed October 11, 2011 (FDA Reference No.: E-2011-021/US-02).
- II. U.S. Patent granted April 22, 2014: U.S. Patent 8,704,169 B2 (FDA Reference No. E-2011-

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to manufacture and commercialization of a field-deployable mass spectrometer diagnostic for the rapid detection of SARS, SARS-CoV-2 and other viruses, bacteria and bacterial serovar, and drug impurities.

Above listed patent covers inventions directed to a mass spectrometer for analyzing samples suspected of having microorganisms. It is also directed to methods for generating a mass spectrum profile of a sample.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless within 15 days from the date of this published notice, FDA receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 9, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

